

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re the Application of: Kantor, et al.	)	
Serial No.:	)	Group Art Unit: 1641
Filed:	)	Examiner: Cheu, C.J.
Atty. File No.:	)	Conf. No.: 3053
	)	
For: "BIOMARKERS FOR DIAGNOSING RHEUMATOID ARTHRITIS"	)	<u><b>RESPONSE TO RESTRICTION REQUIREMENT</b></u>

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Office Action was mailed in the above-captioned application on June 2, 2006. In such Office Action claims 1-52 were pending. Claims 1-52 were subject to restriction and/or election requirement. This Response to Restriction Requirement document is submitted in response to said Office Action.

**Restriction Requirement under 35 U.S.C. § 121**

An election requirement was made to pending claims 1-26. The claims were placed into ten groups:

- Group I (claims 1, 44, 49-52) drawn to an isolated amino acid marker from Table 1-4;
- Group II (claims 1, 44, 49-52) drawn to isolated polynucleotide marker from Table 1-8;
- Group III (claim 2-15) drawn to a method of diagnosing rheumatoid arthritis by using the marker from Table 1-8;
- Group IV (claims 16-29) drawn to a method of diagnosing rheumatoid arthritis by using a plurality of markers from Table 1-8;
- Group V (claims 30-34) drawn to a method of monitoring the progression of rheumatoid arthritis in a subject;
- Group VI (claim 35-37) drawn to a method of assessing the efficacy of a treatment for rheumatoid arthritis by using the marker from Table 1-4;

Group VII (claim 38-40) drawn to a method of assessing the efficacy of a treatment for rheumatoid arthritis by using the marker from Table 5-8;

Group VIII (claim 41-43) drawn to a method for treating rheumatoid arthritis by inhibiting expression of a gene from Table 1-4;

Group IX (claim 45-46) drawn to a method for determining the type, stage or severity of the rheumatoid arthritis in a subject using markers from Table 1-8; and

Group X (claim 47-48) drawn to a method for determining the risk of developing rheumatoid arthritis in a subject using markers from Table 1-8.

Applicants hereby elect to prosecute the invention of Group IV, claims 16-29, with traverse. The Examiner has further required that a specific marker from Table 1-8 be elected. Applicants hereby elect the marker RA Marker #7, from Table 1, having accession number P01011 and further identified as alpha-1-antichymotrypsin precursor (ACT).

As an initial matter, Applicant respectfully point out that claims of group IV are not limited to a marker of Tables 1-8, but rather a marker as claimed in claim 1. The markers of Claim 1 are markers of Tables 1-8, polypeptide markers of Table 1-4, and homologs and fragments thereof, and polynucleotides (and their complements) which encode polypeptides markers of Table 1-4, and homologs and fragments thereof. Nonetheless, Applicant has elected the marker RA Marker #7, which appears in Table 1.

The rejection reasons that each marker is patentably distinct because "there is no core-structure sharing among each marker" and concludes that an election requirement is proper on this basis. Applicants note that there is a structure relationship among at least some of the markers in Tables 1-8. For example, Table 1 recites polypeptide markers found to be increased in rheumatoid arthritis (RA), and Table 3 recites fragments of those polypeptides. Similarly, Table 2 recites polypeptide markers found to be decreased in RA, and Table 4 recites fragments of those polypeptides. Applicants submit that a search for a polypeptide marker, which would encompass the markers of Tables 1 and 2, would also necessarily encompass the polypeptide fragments of Tables 3 and 4. Thus the reasoning for the requirement for election is in error.

Even if the reasoning were not in error, Applicants submit that this reasoning is not relevant to the elected group as the elected group is not directed to the markers themselves. In a

search for methods for diagnosing RA, the “core structure” of the marker would not necessarily be searched.

Applicants traverse the restriction requirement between Groups III and IV on the grounds that no serious burden exists to perform a search for the invention of Groups III and IV. The Patent Office may require restriction if two or more “independent and distinct” inventions are claimed in one application. However, “if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” M.P.E.P. § 803. Applicant submits that a thorough search for Group IV should also include the subject matter of Group III. In the present case, the subject matter of these groups cited by the Examiner is sufficiently small and so closely related as to be capable of examination together, even though the subject matter of Group III and IV relate to distinct and independent inventions. The Restriction Requirement in this case only serves to increase the prosecution expense to the applicants and to the Patent and Trademark Office.

More specifically, with regard to the restriction between Groups III and IV, the two independent claims in the respective groups are Claims 2 and 16. The subject matter of Claim 2 is highly related to the subject matter of Claim 16, in that both claims are directed to a method of diagnosing RA, comprising obtaining a biological sample from the subject, determining the level of a marker in the sample; and comparing the level of the marker in the sample to a standard level or reference range. The claims differ in that Claim 16 is directed to more than one marker. Thus, in effect, Claim 2 simply claims a more narrow embodiment of the subject matter of Claim 16.

The Office action indicates that the feature of determining a plurality of markers for diagnosing RA in Group IV is not required by the other groups. Applicants respectfully point out that the claims of Group IV do not require the feature of “determining a plurality of markers.” Rather, the claims recite “determining the level of a plurality of markers” where one of the markers is a marker of claim 1.

For the foregoing reasons, Applicants submit, that for the Examiner to do a search of the full scope of Claim 16 of Group IV, the subject matter of Group III will necessarily be searched, as well. Applicants request that the Examiner reconsider and withdraw the restriction requirement between Group III and Group IV.

Similarly, the independent claims of Groups IX, and X contain the steps of obtaining a biological sample from the subject, measuring the level of a marker in the sample, and comparing the level of the marker measured in the sample to a standard level or reference range. Applicants submit that in a search of the full scope of Group IV, the subject matter of Groups IX and X is overlapping with Group IV to an extent that there would be no undue burden in performing a search of the subject matter of Groups IX and X. Applicants therefore request that the Examiner reconsider and withdraw the restriction requirement between Group IV and Group IX and X.

Regarding Groups V, VI, and VII, these groups also contain subject matter that is overlapping with Group IV to an extent that there would be no undue burden in performing a search of the subject matter of Groups V, VI, and VII in a search for the full scope of Group IV. Each of these groups recites the same basic method steps as in the claims of Group IV, with small variations. For example, Group V requires the measurement of a marker in two different samples and comparing these to each other, rather than a reference range. Groups VI and VII require the measurement of a marker at two different time points, and comparison of these marker levels to each other, rather than to a reference value. In effect, the claims of Groups V, VI, and VII, are simply varying embodiments of the subject matter of Claim 16. Applicants therefore request that the Examiner reconsider and withdraw the restriction requirement between Group IV and Groups V, VI, and VII.

#### Closing Remarks

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

Although it is believed that no fees are due with this submission, the undersigned hereby

authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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